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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|-----------------------|------------------------|------------------|
| 10/722,508 | 11/28/2003 | Kenneth Carless Smith | 13180-33 | 7663 |
| 1059 | 7590 | 03/14/2006 | EXAMINER | |
| BERESKIN AND PARR 40 KING STREET WEST BOX 401 TORONTO, ON M5H 3Y2 CANADA | | | DRYDEN, MATTHEW DUTTON | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3736 | |

DATE MAILED: 03/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/722,508 | Applicant(s) SMITH ET AL. | |
| | Examiner Matthew D. Dryden | Art Unit 3736 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/28/2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>5/17/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claim 8 is objected to because of the following informalities: recites the limitation of the first and second switch but there is no first and second switch in claim 1 which claim 8 refers back to. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 12 and 20-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Skladnev et al (6845264).

Regarding claim 1, Skladnev et al discloses an apparatus for recognizing tissue types comprising:

a multiplexing unit (element 115 Figure 5),

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N body leads for electrically connecting the multiplexing unit to the body part (see elements 110-113 in Figure 5),

and a controller-switching unit for allowing a current to flow through the body part between body leads, n1 and n2, and a voltage to be measured between two body leads, n3 and n4 (can be either the CPU in Figure 5, pulse switch 117, element 127 or the two different channels hooked up to the multiplexer).

Regarding claim 12,

providing a multiplexing unit (see Column 8, lines 59-62),

connecting the body part to the multiplexing unit with N body leads (see Column 7, lines 1-61),

sending a current through the body part between two body leads and measuring a resultant voltage between two body leads (see Columns 8-9, lines 59-51 and column 4, lines 26-40).

Regarding claim 20,

a module is defined as a computer circuit consisting of an assembly of electronic components, the device of Skladnev et al has an impedance module which is viewed as a computer circuit that generates current for the input current lead,

measuring the resultant voltage (see Column 9, lines 30-33) with the impedance module,

and calculating an impedance from the current and the resultant voltage (see Column 9, lines 34-36).

Regarding claim 21, see Column 9, lines 38-56.

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Regarding claim 22,

a multiplexing unit (element 115 Figure 5),

N body leads for electrically connecting the multiplexing unit to the body part (see elements 110-113 in Figure 5),

a controller switching unit adapted to allow both bipolar and tetrapolar measurements using the N body leads (can be either the CPU in Figure 5, pulse switch 117, element 127 or the two different channels hooked up to the multiplexer regarding tetrapolar measurements see column 4, lines 26-30, bipolar see Columns 8-9, lines 59-56).

Regarding claim 23,

a multiplexing unit (element 115 Figure 5),

N body leads for electrically connecting the multiplexing unit to the body part (see elements 110-113 in Figure 5),

a controller switching unit adapted to allow a) a particular one of the N body leads to inject current into the body part for measuring a first resultant electrical property in a first measurement, and b) the particular one of the N body leads to measure a second resultant electrical property that results from injecting current into the body part in a second measurement (see Column 4, lines 26-30, and columns 8-9, lines 59-56).

Regarding claim 24, see columns 8-9, lines 59-56, specifically Column 8, lines 62-67, and lines 13-40 in Column 9.

Regarding claim 25,

providing a multiplexing unit (element 115 Figure 5),

connecting the body part to the multiplexing unit with N body leads (see Column 7, lines 1-61),

sending a current into the body pad via a particular one of the N body leads to obtain a first resultant electrical property in a first measurement (see Column 4, lines 26-30, and columns 8-9, lines 59-56),

injecting current into the body part in a second measurement (see Column 4, lines 26-30, and columns 8-9, lines 59-56),

and measuring a second resultant electrical property with the particular one of the N body leads in the second measurement (see Column 4, lines 26-30, and columns 8-9, lines 59-56).

Regarding claim 26, see columns 8-9, lines 59-56, specifically Column 8, lines 62-67, and lines 13-40 in Column 9.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-6, 8, 13-17 are rejected under 35 U.S.C. 103(a) as being patentable over Skladnev et al in view of Boone et al (5919142). Regarding claims 2 and 13, Skladnev et al discloses the claimed invention and method except for the device comprising specific leads for connecting the controller-switching unit to the multiplexer. Boone et al teaches it is known to provide an electrical impedance apparatus with leads

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connecting the switching means to the multiplexer so that electrodes may be selected for application of a fixed current according to a desired excitation sequence (see Column 4, lines 11-14). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Skladnev et al with leads for connecting the switching means with a computer and multiplexer, as taught by Boone et al, so that electrodes may be selected for application of a fixed current according to a desired excitation sequence.

Regarding claims 3 and 14, Skladnev discloses the claimed invention except for the first switching means to comprise the injecting electrodes, and the second switching means to comprise the current output. Boone et al teaches it is known to provide voltage leads to each switch for selecting specific electrodes for application of a fixed current (see Column 4, lines 11-14), which could also read on selecting specific electrodes for measuring the voltage across the electrodes. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Skladnev

Regarding claim 4, Skladnev teaches a switching unit that allows for measurements in either a bipolar mode or a tetrapolar mode (see Columns 3-4, lines 49-50, and columns 8-9, lines 60-61).

Regarding claims 5 and 16, for a bipolar measurement to take place one of the electrodes must supply the current and the other electrode must sense the voltage so the device as modified of Skladnev et al discloses the claimed invention where the first voltage lead and current input lead are connected to either the first MX lead and the

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second MX lead, which is element 111 in Figure 5, and the current output lead and second voltage lead is connected to the third or fourth lead, element 112.

Regarding claims 6 and 17, see rejection of claim 5 above except now the current and voltage leads are connected to both stimulating electrodes 110, 111, and the current output lead is connected to one of the third and fourth leads while the second voltage lead is connected to the other one (see Columns 3-4, lines 49-30).

Regarding claim 8, Skladnev et al discloses the claimed invention except for the controller-switching unit including a controller for controlling switch states and multiplexing states. Boone et al teaches it is known to provide a computer for controlling the multiplexer, which in turn would control the switches and multiplexer states so that specific electrodes can be selected for a desired effect and sequence. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Skladnev et al to include a controller for controlling switch states and for controlling multiplexing states, as taught by Boone et al, so that specific electrodes can be selected for a desired effect and sequence.

Regarding claim 15, Skladnev et al discloses the claimed invention and method corresponding to placing the controller-switching unit in a tetrapolar mode (see Column 4, lines 26-30, and columns 8-9, lines 59-56).

Claims 7 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skladnev et al in view of Papa (4184486). Skladnev et al discloses the claimed invention and method except for the leads having an internal load connected to the leads. Papa teaches it is known to provide a sensor device with an internal load on the

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lead (see Column 3, lines 24-52) to allow for measuring of the electrode and determining whether or not internal load has been diminished by short-circuiting. Also Skladnev et al teaches a resistor inside the leads of the their apparatus which can be viewed as an internal load. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Skladnev et al with an internal load, as taught by Papa,) to allow for measuring of the electrode and determining whether or not internal load has been diminished by short-circuiting.

Claims 9-11 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skladnev et al in view of Faupel (5415164). Skladnev et al discloses the claimed invention and method except for the body part under investigation being the breast, however Skladnev et al does teach it is known to place the apparatus on a cancerous tissue or skin portion. Faupel teaches it is known to provide an apparatus and method for diagnosing disease in body tissues over a breast to measure the gradient of electrical activity for determining the disease conditions in an area of the breast(see Columns 4-5, lines 54-28). It would have been obvious to one having ordinary skill in the art at the time the current invent was made to modify the device and method of Skladnev et al to place the apparatus on the breast, as taught by Faupel, to measure the gradient of electrical activity for determining the disease conditions in an area of the breast.

Regarding claim 10, Skladnev et al discloses this part of the invention see rejection of claim 20.

Regarding claim 11, see rejection of claim 21 above.

Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Pat. No. 4,291,708 Frei et al disclose an apparatus and method for detection of tumors in tissue

U.S. Pat. No. 6,584,348 Glukhovsky discloses a method for measurement of electrical characteristics of tissue

U.S. Pat. No. 6,625,487 Herleikson discloses a bioelectrical impedance ECG measurement and defibrillator implementing the same.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew D. Dryden whose telephone number is (571) 272-6266. The examiner can normally be reached on Monday-Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MDD



MARK H. GENTRY
PATENT EXAMINER
UNIT 3736